

Approval Date: April 20, 2007

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-460

**TETROXY Aquatic
(oxytetracycline hydrochloride)**

**Indications for use: To mark skeletal tissues, most often the
otoliths, of all finfish fry and fingerlings for subsequent
identification.**

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-460
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24, Ireland
- Drug Labeler Code: 061623
- c. Established Name: Oxytetracycline hydrochloride
- d. Proprietary Name: TETROXY Aquatic
- e. Dosage Form: Soluble powder
- f. How Supplied: 3.45 lb (1.57 kg) (1565 grams) pouch
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Oxytetracycline hydrochloride 366 mg/g of powder
- i. Route of Administration: Immersion water
- j. Species/Class: Finfish
- k. Recommended Dosage: 200-700 mg oxytetracycline hydrochloride (buffered)/liter of water for 2-6 hours depending on species
- l. Pharmacological Category: Antimicrobial
- m. Indications: To mark skeletal tissues, most often the otoliths, of all finfish fry and fingerlings for subsequent identification.
- n. Pioneer Product: OXYMARINE; oxytetracycline hydrochloride; NADA 130-435; Alpharma, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product TETROXY Aquatic (oxytetracycline hydrochloride). The generic product is administered as a soluble powder to be immersed in water, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, OXYMARINE (oxytetracycline hydrochloride), the subject of Alpharma, Inc., NADA 130-435, was approved on December 24, 2003.

3. HUMAN SAFETY:

Human Warnings are provided on the product label as follows: Keep Out of Reach of Children.

- **Tolerances for Residues:**

The tolerance established for the pioneer product applies to the generic product. A tolerance 2 parts per million (ppm) is established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in muscle under 21 CFR 556.500.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product (21 CFR 529.1660).

The withdrawal time beyond the grow-out period is not needed.

- **Regulatory Method for Residues:**

The analytical method for detection of residues of oxytetracycline is a microbiological assay using *Bacillus cereus* var. *mycoides*. This method may be found in “Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols” (revised October 1968, reprinted December 1974), National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204). The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the immersion product TETROXY Aquatic, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-460:

TETROXY Aquatic – Container Label – 3.45 lb pouch

Pioneer Labeling for NADA 130-435:

OXYMARINE – Container Label – 3.45 lb pack